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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

PLAINTIFFS' REPLY CLAIM CONSTRUCTION BRIEF (PATENT L.R. 4-5(c))

Markman Hearing
Date: June 25, 2008
Time: 2:00 p.m.
Room: Courtroom 6, 4th Floor
Judge: Hon. Ronald M. Whyte

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STATUTES

Plaintiffs Hologic, Inc., Cytyc Corporation, and Hologic L.P. (collectively "Hologic") respectfully submit this Reply Brief addressing SenoRx, Inc.'s ("SenoRx") proposed construction of disputed terms, phrases, and clauses in the asserted claims of U.S. Patent Nos. 5,913,813 (the "'813 patent"), 6,413,204 (the "'204 patent"), and 6,482,142 (the "'142 patent") (collectively, "the patents-in-suit").

PRELIMINARY STATEMENT

SenoRx's proposed constructions of the disputed claim terms should be rejected. Even a cursory review of SenoRx's proposed constructions reveals a tactic repeated time and time again – the attempt to add limitations where none exist, thereby narrowing the inventions that the patentee sought and was granted by the PTO. For the most part, SenoRx's claim construction methodology is contrary to applicable Federal Circuit precedent. For example, by reading the words "concentric" and "spherical" into certain claim terms, SenoRx seeks to impose on the claimed inventions a degree of geometrical precision that is neither required by the plain language of the claim, nor counseled by the specification. Indeed, the relevant portions of the specifications teach that geometric precision is unnecessary, evidenced by the use of terms such as "generally" and "substantially." Further, SenoRx attempts to construe the claims to exclude embodiments that the plain meaning of the claims would otherwise cover. In some instances, SenoRx attempts to read the claims to exclude *all* of the disclosed embodiments. This, of course, is in all but the rarest cases impermissible.

SenoRx's proposed constructions run afoul of other fundamental claim construction principles. For example, in another effort to narrow the claimed inventions, SenoRx contends that "predetermined constant spacing" means the same thing as "predetermined spacing." In so arguing, SenoRx disregards the glaring difference between these terms on their face, ignores language from the specification confirming that they mean different things, discounts the Court's own prior ruling that these two terms have different meanings, and overlooks clear Federal Circuit precedent that where a patentee uses different terms, those differences are presumed to reflect a difference in claim scope.

Finally, in some instances, SenoRx simply misunderstands the import of the intrinsic record and how that record applies to the claims. In these cases, SenoRx again defaults to the narrowest

interpretation of the claim terms that it can conceive, notwithstanding the broad language actually used in the claims. Claim construction is not an exercise of juxtaposing the accused product and the disputed terms and concocting a construction that removes the accused device from the scope of the invention. Hologic respectfully requests that its proposed constructions, which (with one exception) are consistent with the Court's prior construction of many of these same terms, more accurately reflect the plain meaning and the teachings of the intrinsic evidence. Thus, SenoRx's proposed constructions should be rejected.[1]

ARGUMENT

I. THE '813 AND '204 PATENTS

A. "Predetermined Constant Spacing" and "Predetermined Spacing" - SenoRx's Proposed Constructions Ignore Clear Differences in the Claim Language and Usage in the Specification

The term "predetermined constant spacing" appears in claim 1 of the '813 patent, whereas the facially broader term "predetermined spacing" appears in claim 3 of the '204 patent.[2] SenoRx suggests that "predetermined constant spacing" and "predetermined spacing" should be construed as meaning ***exactly the same thing***, despite apparent differences in the phrases themselves. In so doing, SenoRx ignores the general rule that different claim terms are presumed to reflect a different scope. As described in further detail below, Hologic's proposed construction stays true to the express language of the claim and is consistent with the intrinsic evidence.

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[1] Many of the claim terms at issue here have already been disputed, briefed, argued by litigants, and construed by this Court in a prior infringement action involving two of the three patents asserted here. *Xoft, Inc. v. Cytyc Corp. et. al*., Case No. C-05-05312 RMW (the "Xoft litigation") (involving both the '813 and '204 patents). With one exception (discussed below), Hologic agrees with all of the Court's prior constructions. Conversely, with one exception, SenoRx disagrees with all of the Court's prior constructions but it fails to offer any persuasive reason why the prior constructions are wrong.

[2] The '813 patent and the '204 patents are related and share common subject matter between their respective specifications. The '204 patent is a continuation-in-part of the '813 patent due in part to the disclosure of additional subject matter.

1. "Predetermined Constant Spacing Between Said Inner Spatial Volume and the Radiation Transparent Wall" - SenoRx's Construction Adds Limitations That Are Not Supported (Claim 1, '813 Patent)

Hologic urges that the Court adopt its previous construction of this term, *i.e.*, "spacing determined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical." Dkt. No. 135-6 at 6-7, 28 (Claim Construction Order from the Xoft litigation). SenoRx offers no principled basis for altering the Court's prior construction. SenoRx's proposed requirement of a "fixed" spacing – such that, "*for each point* on the wall or edge of the inner spatial volume, the distance *to the closest point* on the outer chamber is the same" – is contradicted by the specification, which counsels against reading the claim term "constant" too narrowly. For example, the specification states that one objective is to keep the distance between the inner spatial volume and the radiation transparent wall "substantially constant," '813 patent, 1:50-57, "generally constant," *id.* at 3:10-13, "somewhat constant," *id.* at 4:13-16. These words confirm that the spacing is not "fixed" or "the same." The specification's less restrictive description of the claim element is consistent with its description of the radiation transparent wall as conforming tissue to the surface of the balloon; such a wall inherently would not be "fixed" or at the same distance from the wall of the inner spatial volume "*for each point* on the wall or edge of the inner spatial volume," as SenoRx incorrectly contends.

Moreover, SenoRx's proposed construction ignores the practical limitations of radiotherapy that existed in 1997 and today. Verhey Decl. ¶¶ 4-5. Brachytherapy balloons and the lumpectomy margins against which they are expanded are generally spherical in shape but cannot be *perfect* spheres. *Id*. The patent's specification expressly recognizes this limitation by avoiding words of exactitude. *Id.* SenoRx's narrow reading of this claim term to require a "fixed" spacing is divorced from the specification and the understanding of one skilled in the art, and should be rejected.

SenoRx also insists that the inner spatial volume and the outer wall must be "concentric" and "the same shape." The Court has already construed this term and concluded that no such limitations are required or supported by the specification. While the patentee clearly contemplated configurations

having concentricity and similarly shaped surfaces, it specifically chose ***not*** to limit claim 1 to such configurations or embodiments. SenoRx's repeated references to the patent figures are unavailing because the claimed invention is not limited to specific examples or embodiments set forth in the specification. *Id*. If the patentee had intended to so limit the invention's scope, then he would have said so. SenoRx's proposed additional limitations should be rejected.

2. "Predetermined Spacing . . . Between Said Inner Spatial Volume and the Expandable Surface Element" – SenoRx Ignores Clear Differences in Claim Language (Claim 3,[3] '204 Patent)

SenoRx ignores the fact that the phrase "predetermined spacing" in the '204 patent is facially broader than the term "predetermined constant spacing" used in the '813 patent. When read in light of the specification and file history of the '204 patent, "predetermined spacing" must be given a broader meaning than "predetermined constant spacing." Indeed, that is exactly what the Court did in the Xoft litigation when it broadly defined this term to mean that "the distance between the inner spatial volume and the expandable surface element is determined in advance." Dkt. No. 135-6 at 24-25 (Claim Construction Order from Xoft litigation). The Federal Circuit has held that "[w]here claims use different terms, those differences are presumed to reflect a difference in the scope of the claims." *Forest Labs, Inc. v. Abbott Labs.*, 239 F.3d 1305, 1310 (Fed. Cir. 2001); *cf. Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*) ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.")

SenoRx is unable to point to any intrinsic evidence suggesting that "predetermined spacing" is the same as "predetermined constant spacing." As Hologic demonstrated in its initial claim construction brief, the plain meaning of "predetermined spacing" – *i.e.* "the distance between the inner spatial volume and the expandable surface element," which is "determined in advance" – should be adopted. Dkt. No. 134 at 16. SenoRx's reference to Dr. Verhey's prior declaration misses the point. Dkt. No. 130 at 8. The fact that the spacing *can be* predetermined or made substantially constant does not mean the claim *requires* a "constant" spacing. Verhey Decl. ¶¶ 6-7.

[3] This term appears in claim 3, on which asserted claim 4 depends.

B. "Three-Dimensional Isodose Profile" - SenoRx Improperly Reads "Concentricity" and "Finality" into the Claims (Claim 1, 17, '204 Patent)

The term "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element" means just that; the plain meaning is apparent without altering the language used by the patentee. Again, SenoRx attempts to add limitations, this time suggesting that the term requires (1) that the isodose profile be "concentric with the outer spatial volume expandable surface," and (2) that the isodose profile be "final." Dkt. No. 130 at 8-11 (SenoRx's Opening Claim Construction Brief). These additional limitations are not supported by the intrinsic evidence.

First, SenoRx improperly conflates specification and prosecution statements regarding the claim language "substantially similar in shape" with the notion of "concentricity." In the specification, when the patentee described an embodiment requiring concentricity, it expressly stated so. *See* '204 patent, col. 5:28-29 ("In either the *concentric* spherical embodiment or the non-spherical configuration of FIG. 5 . . . .").[4] Moreover, contrary to SenoRx's contention, "concentricity" was not the basis upon which the inventors distinguished their inventions from the prior art during prosecution before the PTO. The prosecution statements describing "a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element" do not mean that the "three-dimensional isodose profile" must be "concentric," as SenoRx suggests. The mere fact that the balloons in the Williams prior art discussed by the application were not concentric does not provide a basis for limiting the claims to concentric embodiments. Importantly, the arguments accompanying the addition of the "substantially similar in shape" element do not point out or distinguish the Williams balloons as being non-concentric. *Cf. Micro Chemical, Inc. v. Great Plains Chemical Co., Inc.*, 194 F.3d 1250, 1260-61 (Fed. Cir. 1999) (finding statements used during prosecution describing differences between the claim and prior art were only relevant to the extent that the difference was recited in the claim—and were not relevant to unclaimed features). It would be inappropriate to limit the claimed invention based on distinctions the inventors did not draw during prosecution. *Cf. Computer Docking Station Corp. v.*

[4] In fact, the word "concentric" appears only once in the entire specification.

Dell, 519 F.3d 1366, 1376 (Fed. Cir. 2008) ("Prosecution disclaimer does not apply, for example, if the applicant simply describes features of the prior art and does not distinguish the claimed invention based on those features."). The implicit limitations that SenoRx strains to see in the prosecution history do not exist and cannot "prevail over the plain language of the claim." *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1373 (Fed. Cir. 2007). The prosecution statements in this instance are far from being the requisite "clear and unmistakable" statements necessary to require the importation of concentricity into the phrase "substantially similar in shape," SenoRx's arguments notwithstanding. *See* Verhey Decl. ¶¶ 8-9.

Second, by adding the word "final" to its proposed construction (which is not found in either the claim language or anywhere the specification), SenoRx improperly attempts to import a temporal limitation into the term "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element." To support its construction, SenoRx mischaracterizes the purposes of the invention and proffers unhelpful, conclusory expert testimony. The '204 patent describes two primary purposes of the invention: one purpose is to provide a radiation dose delivered to the target tissue that is "substantially uniform in substantially every direction" ('204 patent, 5:13-19) and another is to provide a "predetermined dose range" such that cancerous tissue is destroyed and healthy or "normal" tissue is not destroyed, *i.e.* by necrosis. *See, e.g. id.* at 2:51-55; 6:48-60. Neither of these objectives imposes any requirement of finality; to the contrary, the whole point of the invention is that it will be used flexibly in conjunction with treatment planning software to achieve the desired therapeutic result. One skilled in the art would understand and expect that the desired therapeutic result may call for the dose profile to be modified or adjusted. Accordingly, there is no such thing as a "final" isodose profile. Moreover, as stated previously (dkt. no. 134 at 17), inserting the word "final" into the claim would render the claim vague rather than provide clarification (how would a jury determine when an isodose profile is to be considered "final"). Verhey Decl. ¶ 9. Accordingly, this term should be construed to mean what it says, namely a "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element," and nothing more.

C. "Inner Spatial Volume" - SenoRx Would Improperly Limit the Claim To Only the Preferred Embodiments

The claim term "inner spatial volume" appears in claim 1 of the '813 patent and claim 3 of the '204 patent.[5] Again, the meaning of this term was briefed and argued in the prior Xoft litigation and it should mean what the Court construed it to mean, with one modification – "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide []." Dkt. No. 135-6 at 3-5 (Claim Construction Order in Xoft litigation.) SenoRx's proposed changes to the Court's prior construction are overly narrow and impermissibly import aspects of certain embodiments from the disclosure into the claims. Specifically, the parties disagree on whether the term "distensible" should be read into the claim and whether, when the inner spatial volume is a radionuclide, it must be "spherical." In both cases, SenoRx's attempt to import these limitations from the specification is improper. Hologic's proposed construction should be adopted because it "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Phillips*, 415 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d at 1243, 1250 (Fed. Cir. 1998)).

1. There Is No Justification for Importing "Distensible" into the Claim

SenoRx contends that the specification of the '813 and '204 patents "consistently describe" the "inner spatial volume" as being distensible, thus "mak[ing] clear that the polymeric film walls must be distensible." Dkt. No. 130 at 12 (SenoRx's Opening Claim Construction Brief). To the contrary, the specification never says that an "inner spatial volume" has to be distensible if it is a polymeric film wall:

- "Affixed to the tubular body 12 proximate to the distal end 28 thereof is an inner spatial volume 30 which may be defined by a generally spherical polymeric film wall 32." '813 patent, 2:33-36; '204 patent, 3:57-59;
- "Those skilled in the art will appreciate that instead of having the inner spatial volume 30 defined by a generally spherical polymeric film wall as at 32 . . . ." '813 patent, 2:56-58;

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[5] SenoRx and Hologic agree that this term should have the same meaning in both the '813 and '204 patents.

- "[I]nstead of having the inner spatial volume 30 defined by a generally spherical polymeric film wall as at 32 . . . ." '204 patent, 4:44-46;
- "It is not essential to the invention that the chambers 30 and 34 have spherical walls . . . ." '813 patent, 3:10-11;
- "[W]herein said inner spatial volume is an inner closed, chamber defined by a further radiation transparent wall." '813 patent, 4:53-55 (claim 2);
- "[R]adioactive source material . . . may be coated on, chemically bonded to, or copolymerized with the material forming inner spherical wall 32." '204 patent, 4:24-27.

These passages from the '813 and '204 patents describe embodiments in which the inner spatial volume is a "polymeric wall" and nowhere is there a requirement that it be "distensible." As the Federal Circuit has held, "varied use of a disputed term in the written description attests to the breadth of the claim term rather than providing a limiting definition." *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003). Thus, the proper construction of "inner spatial volume" does not import the limitation "distensible" because doing so would be inconsistent with the varied use of that term in the specification. *Id.*

In addition, the prosecution history of the '813 patent demonstrates that the inventors did not limit their claims to an "inner spatial volume" with a "distensible" polymeric film wall. For example, the original claims filed in connection with the application that became the '813 patent, original claim 2, recited that the "inner spatial volume is an inner closed, distensible chamber." Dkt. No. 135-10 at 1-2. That claim was amended to ***broaden*** the language by deleting the term "distensible" so that the claim called for an "inner spatial volume" that "is an inner closed chamber." *Id.*; *see also* '813 patent, 4:53-55. By this amendment, the inventors clearly expressed their intent—consistent with the scope of the specification—that the "inner spatial volume" need not be "distensible." It would be improper to ignore "the effect of [this amendment] on the scope of the claims." *See Libel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004).

Other claims of the '813 and '204 patents "provide substantial guidance as to the meaning of" the "inner spatial volume" claim term. *Phillips*, 415 F.3d at 1314. Comparing claim 2 of the '813 patent and claim 9 of the '204 patent demonstrates that the "inner spatial volume" may or may not be

distensible. *Compare* '813 patent, 4:53-55 ("wherein said inner spatial volume is an inner closed, chamber defined by a further radiation transparent wall") *with* '204 patent, 8:59-61 ("wherein the inner spatial volume is an inner closed distensible chamber defined by a further radiation transparent wall" (emphasis added)). Again, if the inventors wanted to claim an invention more narrowly, they knew how to do so by adding the word "distensible" to an "inner closed chamber." *See* Verhey Decl. ¶¶ 10-11. This is no different from the situation in *Phillips*, in which the selective use of the term "steel" makes clear that the term "baffles" does "not inherently mean objects made of steel." 415 F.3d at 1314. Thus, there is no reason to limit the even broader term "inner spatial volume" to structures that are "distensible."

2. Limiting the "Inner Spatial Volume" to a Radionuclide "Sphere" Improperly Limits the Claim to Preferred Embodiments

SenoRx requests that the Court read the term "spherical" into the meaning of "inner spatial volume." SenoRx places substantial weight on this Court's construction of "inner spatial volume" from the *Xoft* litigation as limiting the claim to a polymeric film wall or a "radionuclide ***sphere***." Dkt. No. 130 at 11-13 (SenoRx's Opening Claim Construction Brief). It must be noted that the question of whether a "radionuclide" must be spherical when the "inner spatial volume" is a radionuclide was not briefed by either party in the Xoft case, nor was it relevant to the resolution of any issues raised in that case. *See* Dkt. No. 134 at 6 n.5 (Hologic's Opening Claim Construction Brief). With the Court and the parties now focused on this issue, it becomes apparent from the intrinsic evidence that radionuclides comprising the "inner spatial volume" do not need to be (but can be) spherical.

Requiring that radionuclide inner spatial volumes be spherical imports features of a preferred embodiment from the specification into the claims, in derogation of the general disclosure in the specification, which provides that "[i]t is not essential to the invention that the chambers 30 and 34 [*i.e.* the inner and outer volumes] have spherical walls . . . ." '813 patent, 3:9-10; '204 patent, 5:13-16. The specifications of both the '813 and '204 patents include a number of exemplary embodiments. Among these are two principal embodiments (each of which has numerous variations): (1) an embodiment in which the inner and outer spatial volumes are "generally spherical," (*e.g.* '813 patent,

1:35; Fig. 1), and (2) one in which the inner and outer spatial volumes are non-spherical. (*e.g.* '813 patent, 3:9-14; Fig. 3). Nothing in the specification—or elsewhere in the intrinsic record—limits solid radionuclides to embodiments where they are "generally spherical." Rather, it describes "radioactive particles," '813 patent, 2:66, "radioactive beads," '813 patent, 3:3, "solid radioactive core[s]," '813 patent, 4:6-7, '204 patent, 4:56, "solid radionuclides," '813 patent, 4:9; '204 patent, "radiation emitting particles," '204 patent, 5:3-4, or "radioactive particle sources," '204 patent, 5:35. None of these passages requires the radionuclide to be "spherical." To the contrary, the specification makes the point that "[s]olid radionuclides that could be used with the delivery device of the present invention are currently generally available as brachytherapy radiation sources," '813 patent, 4:10-12; '204 patent, 4:58-61, and "radioactive micro spheres" are merely one example that was then available from a particular vendor, '813 patent, 4:1-3; '204 patent, 4:48-50. *See also* Verhey Decl. ¶¶ 12-13 (explaining that the invention's objectives can be achieved whether or not the radionuclide is spherical, and noting that both spherical and non-spherical radionuclides in this context are effectively point sources); *see also* Dkt. No. 135-7 at 3-4 (Verhey Decl., noting that in 1997, radionuclides used in brachytherapy were often not spherical). Thus, the claim term "inner spatial volume" should not be limited to "spherical" radionuclides because the intrinsic record read as a whole supports a broader construction. *See Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1373-76 (Fed. Cir. 2005) (refusing to construe term "saccharides" as being limited to sugars despite a reference in the specification to "saccharides" (*i.e.*, sugars)).

It is improper to "add a narrowing modifier [i.e., "spherical"] before an otherwise general term [radionuclide] that stands unmodified in a claim . . . ." [citations omitted]. For example, if an apparatus claim recites a general structure *e.g.,* a noun [inner spatial volume] without limiting that structure to a specific subset of structures (*e.g.,* with an adjective [*e.g.*, "spherical"]), we will generally construe the claim to cover all known types of that structure that are supported by the patent disclosure. *Reinshaw PLC*, 158 F.3d at 1249-50. To do otherwise improperly imports aspects of preferred embodiments into the claims—thereby violating fundamental Federal Circuit precedent. *See, e.g.*, *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quoting *CollegeNet, Inc. v.*

ApplyYourself, Inc., 418 F.3d 1225, 1231 (Fed. Cir. 2005) for the proposition that "[i]n examining the specification for proper context, however, this court will not at any time import limitations from the specification into the claims").

D. "Means . . . For Rendering Uniform" - SenoRx's Proposed Construction Impermissibly Adds An Unclaimed Function ('813 Patent, Claim 1)

The parties agree that this term is a means-plus-function element and is subject to 35 U.S.C. § 112, ¶ 6, requiring the identification of the claimed function and corresponding structure.[6] Hologic requests that the Court construe this term as it did the first time. SenoRx seeks to add limitations to the Court's previous construction of both function and structure.[7] SenoRx first argues that the absorbed dose profile must be rendered "substantially" more uniform (rather than simply "more uniform" – as the Court previously concluded). SenoRx further contends that the structure must perform the stated function (*i.e*. rendering the dose more uniform) "by absorbing or attenuating radiation"—despite the claim making no reference to this additional requirement.

First, SenoRx identifies no justification for requiring that the absorbed dose profile be rendered "substantially" more uniform, rather than simply "more uniform" – as the Court previously decided. This proposed change adds nothing but ambiguity to the claim term. Verhey Decl. ¶ 15. Dr. Orton's assertion that some radiation absorbing or attenuating materials, in conjunction with a low energy source, *can* "significantly affect the dose versus distance curve" (dkt. no. 132 at 11) provides no basis for narrowing the claim term by *requiring* that the absorbed dose profile be rendered "substantially" more uniform. *Id*.

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[6] *BBA Nonwovens Simpsonville, Inc. v. Superior Nonwovens, L.C.C.,* 303 F.3d 1332, 1343 (Fed. Cir. 2002) (construction of means-plus-function claims requires identification of claimed function and corresponding structure).

[7] The parties agree that the corresponding structure is "a radiation absorbing or attenuating material." Dkt. No. 130 at 14 (SenoRx's Opening Claim Construction Brief). Moreover, both parties agree that the specification discloses certain materials that, if they or their equivalents are present in the accused device, are encompassed within the literal scope of the claim (*e.g.*, air, x-ray attenuating material, contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate, and their equivalents). *Id*. SenoRx, however, believes that these materials must perform a function ***other than that recited in the claim***.

Second, it is well settled that the addition of an unstated functional limitation to a claim, as urged by SenoRx, is impermissible. *See, e.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1334 (Fed. Cir. 2006) (stating that it is improper to "import[] unclaimed functions into a means-plus-function claim" by "defining a claimed function to require more than is actually claimed"); *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001) ("In construing a means-plus-function limitation, a court must identify both the claimed function and the corresponding structure in the written description for performing that function."). The Federal Circuit has cautioned that where "the recited function is clear on its face, it [is] improper to incorporate . . . additional functional limitation[s]" into the claim." *LG Elecs., Inc. v. Bizcom Elecs., Inc.*, 453 F.3d 1364, 1379 (Fed. Cir. 2006), *cert. granted on other grounds,* 128 S. Ct. 28 (2007). Therefore, SenoRx's proposed construction, which seeks to import an additional function to be performed by the disclosed structure (*i.e.*, the radiation absorbing or attenuating material), should be rejected.

The intrinsic record does not dictate the construction urged by SenoRx. SenoRx contends "the radiation absorbing material must perform the function by absorbing or attenuating the radiation" (dkt. no. 130 at 14) - based on a single embodiment disclosed at column 3, lines 51-65 of the '813 patent. This passage is merely illustrative of how one embodiment performs the recited function. Moreover, that discussion pertains to an embodiment where the attenuating material is in the inner spatial volume and the radionuclide is in the outer spatial volume. *Id.* SenoRx admits that claim 1 also encompasses an embodiment in which the attenuating material is in the outer spatial volume and the radionuclide is in the inner spatial volume. Dkt. No. 130 at 16 (SenoRx's Opening Claim Construction Brief). SenoRx's conclusion from this – *i.e.*, that the material "for performing the claimed function must perform that function by absorbing or attenuating radiation" flies in the face of the claim language, which does not recite a specific mechanism by which the function of "rendering uniform . . ." is performed. Thus, it is impermissible to limit the recited function to a particular scientific mechanism

of "attenuation," as SenoRx proposes.[8] SenoRx's construction improperly imports an unclaimed function into the claim. *See, e.g.*, *LG Elecs.*, 453 F.3d 1364, 1379 (Fed. Cir. 2006).

SenoRx's reliance on the prosecution history also fails to justify the importation of an additional functional limitation. SenoRx ignores the rule that "[f]or a prosecution statement to prevail over the plain language of the claim, the statement must be clear and unmistakable such that the public should be entitled to rely on any 'definitive statements made during prosecution.'" *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d at 1373 (quoting *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003)). Here, the prosecution history does not clearly state that the "means . . . for rendering uniform" must include the function of attenuating or absorbing radiation. Indeed, the prosecution history does not refer to any particular mechanism (such as absorption or attenuation) by which the claimed function is performed—nor did it distinguish the prior art on that basis.[9] *See, e.g.*, Dkt. No. 135-10 at 5 ("There is then provided a means disposed in the chamber, not having the radiation source, for rendering uniform the radial absorbed dose profile of emissions from the chamber that contains the radiation source." (emphasis in original).) Far from constituting a "clear and unmistakable" statement sufficient to overcome the plain language of the claimed function, the prosecution history does not require the function of "rendering uniform" to be performed in any particular way. Therefore, SenoRx's proposed construction should be rejected. *See also* Verhey Decl. ¶ 16 (explaining that SenoRx's proposed language would improperly limit the claim by adding a requirement that is not always true).

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[8] The fact that the specification discloses as corresponding structures materials in the outer spatial volume that attenuate or absorb the radiation of no moment; one cannot conflate the recited function in the claim with the behavior of the corresponding structures disclosed in the specification. All that is required is that the corresponding structures disclosed in the specification perform the *claimed* function.

[9] Rather, the distinction over the Ishiwara *et al*. '360 patent was that the chamber "cannot provide a uniform radiation profile" or how it could be modified to provide a uniform radial absorbed dose profile. Dkt. No. 135-10 at 5.

E. "Inner Closed Chamber" – SenoRx Adds a Limitation Without Support in the Specification ('813 Patent, Claim 11)[10]

This claim term should be entitled to its plain and ordinary meaning. Verhey Decl. ¶ 17. SenoRx appears to agree that "[b]y its plain meaning, this claim further limits the inner spatial volume to a 'closed chamber' or compartment located inside of the outer chamber." Dkt. No. 130 at 17 (SenoRx's Opening Claim Construction Brief). Instead of stopping there, however, SenoRx seeks to add a limitation requiring that the "inner closed chamber" also be "completely inside . . . and closed off within the outer chamber." To support this proposed addition, SenoRx relies only on the conclusory statement of its expert, Dr. Orton. *Id.* This "conclusory, unsupported assertion[]"is "not useful to [the] [C]ourt." *Phillips*, 415 F.3d at 1318.[11] Nor does it make sense as a matter of logic; since the claimed function of the inner closed chamber is to contain the radioactive material (*see* claim 8, from which claim 11 depends), the chamber cannot be "completely inside and closed off within the outer chamber" because then there would be no way of getting the radioactive material into or out of it.

In the absence of any support in the intrinsic evidence for narrowing this claim term, SenoRx's acknowledgement that the plain meaning of "inner closed chamber" is "a 'closed chamber' or compartment located inside of the outer chamber" supports Hologic's construction. Moreover, as set forth in Hologic's Opening Claim Construction Brief (Dkt. No. 134 at 11), the specification and other intrinsic evidence describe embodiments of the invention that would be excluded by SenoRx's unduly narrow claim interpretation. Therefore, SenoRx's interpretation should be rejected.[12]

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[10] This term is found in claim 2 of the '813 patent, on which asserted claim 11 depends.

[11] Indeed, Dr. Orton's testimony as to this claim term consists of one conclusory statement: that "[a] person of ordinary skill in the art would understand the term 'inner closed chamber' to mean an inner chamber completely closed off within the outer, closed, inflatable chamber." Dkt. No. 132 at 11, ¶ 37 (Orton Declaration).

[12] The Court previously found that the term "outer, closed, inflatable chamber" means exactly that – and requires no construction. Dkt. No. 135-6 at 28 (Claim Construction Order in *Xoft v. Cytyc Corp*.) The same should be true for "inner, closed chamber."

F. "Providing a Controlled Dose at the Outer Spatial Volume Expandable Surface to Reduce or Prevent Necrosis in Healthy Tissue Proximate to the Expandable Surface" ('204 Patent, Claim 4)[13]

The Court previously construed a near identical term in the Xoft litigation. Dkt. No. 135-6 at 23. The same construction should apply here. Verhey Decl. ¶¶ 18-20. SenoRx seeks to alter the Court's construction by (1) replacing the language referring to "lethally damaging cells" with "reduce or eliminate the risk of damage . . ."; and (2) adding the phrase "as compared to devices in which the tissue is directly adjacent to the radiation source." Neither proposed addition is supported. As Hologic has shown, those skilled in the art at the time the patent applications were filed understood the term necrosis to mean the death of tissue.[14] SenoRx's construction confuses the plain understanding of reduce or prevent necrosis" by introducing a wholly new and undefined concept: reduce or eliminate "risk of damage." Dkt. No. 130 at 18 (SenoRx's Opening Claim Construction Brief). SenoRx's proposed construction is inconsistent with the specification's description of the process of "necrosis." *See* '204 patent, 6:55-57 ("With increasing cell death comes increasing risk of *necrosis or tissue death in healthy tissue* that is treated with a high dose of radiation." (emphasis added)); *see* Verhey Decl. ¶ 19 (it is impossible to "eliminate the risk of damage" to healthy tissue – as SenoRx suggests). The intrinsic evidence shows that the reduction or prevention of necrosis is achieved by "keep[ing] the maximum radiation dose delivered by the brachytherapy apparatus as low as possible while still delivering the desired therapeutic dose to the desired range of tissue."[15] '204 patent, 6:57-60. The specification reveals no attempt by the inventors to depart from this common meaning of the term "necrosis," as it was understood in the art.

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[13] This term is found in claim 2 of the '204 patent, on which claim 4 depends.

[14] Dr. Orton opines that Hologic's proposed construction "would require avoiding any death to cells in healthy tissue, which is inconsistent with how a person of ordinary skill would understand 'reduce or prevent necrosis in healthy tissue' within the meaning of the claim." Dkt. No. 132 at 17, ¶ 54 (Orton Declaration). That is not an accurate characterization of Hologic's claim construction. Verhey Decl. ¶ 19.

[15] Moreover, the specification teaches that there is an "inherent difference in radiosensitivity between the tumor and the adjacent normal tissues," which permits destruction of "cancerous tissue while causing minimal disruption to surrounding normal tissues." '204 patent, 6:48-52.

SenoRx also seeks to add the requirement that the claimed "controlled dose . . ." must be viewed in light of a single, specific prior art method of operation in which ". . . the tissue is directly adjacent to the radiation source." Dkt. No. 130 at 18 (SenoRx's Opening Claim Construction Brief) (. . . "*as compared to devices in which the tissue is directly adjacent to the radiation source.*"). The specification and claims fail to teach or suggest such a comparison, nor is one required by the intrinsic record. Moreover, such a comparison is impractical—the degree of necrosis (or in SenoRx's terms: "risk of damage") will depend on the amount of energy radiated by the radiation source, the patient's physical profile, as well as its relative proximity to the tissue, as would be understood by those skilled in the art. Verhey Decl. ¶ 20. Thus, Hologic's proposed definition, which stays true to the language of the claim and the inventions described in the specification, is the proper one and should be adopted.

II. SENORX'S PROPOSED CONSTRUCTIONS OF THE TERMS FROM THE '142 PATENT IMPROPERLY DIVORCE INDIVIDUAL TERMS FROM THE REMAINDER OF THE INTRINSIC EVIDENCE[16]

A. "Apparatus Volume" and "Located So As To Be Spaced Apart From the Apparatus Volume" ('142 Patent, Claim 1)

SenoRx's flawed construction of the terms "apparatus volume" and "located so as to be spaced apart from the apparatus volume" forms the basis for its motion for summary judgment that the claimed invention is inoperable, rendering the claims invalid under 35 U.S.C. § 112. Dkt. No. 133. However, SenoRx's claim construction is divorced from the context of the patent, reads out every embodiment described in the specification, and runs contrary to the understanding of one skilled in the art - as well as common sense. SenoRx's position runs counter to the rule that "[a] claim construction that excludes preferred embodiments "is rarely, if ever correct and . . . require[s] highly persuasive evidentiary support." *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)). Moreover, to the extent that SenoRx's construction would render the claims invalid, SenoRx fails to overcome the

[16] Hologic originally asserted claims 1, 6, and 8 of the '142 patent. Based on representations made by SenoRx regarding the accused device after the parties filed their opening claim construction briefs, Hologic has agreed not to assert claim 6. Accordingly, claim 6 is not discussed herein.

statutory presumption of validity, *see* 35 U.S.C. § 282 (2006), which "requires a showing of facts proved by clear and convincing evidence." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1378 (Fed. Cir. 2005). Because the disputed claim terms are easily amenable to a construction that encompasses the preferred embodiments, that stays true to the language of the claim, are consistent with statements made during prosecution of the '142 patent, and are well understood by those skilled in the art, SenoRx's strained constructions should be rejected.

1. An "Apparatus Volume," in the Context of the Claimed Invention, Is a Structure Composed of an Expandable Outer Surface

Hologic's construction of the term "apparatus volume"[17] stays true to the language of the claim, gives effect to what the inventors actually invented, is consistent with the specification, and is reflected in the inventors' statements to the PTO during prosecution of the application that became the '142 patent. Thus, this Court should reject SenoRx's attempt to impose an unduly literal reading on the term "apparatus volume" and adopt Hologic's construction. Verhey Decl. ¶¶ 21-23.

SenoRx contends that Hologic's proposed construction is contrary to (1) Cytyc's position in the *Xoft* litigation; (2) other intrinsic evidence; and (3) the claim language. Dkt. No. 130 at 19 (SenoRx's Opening Claim Construction Brief). On all three points, SenoRx is wrong.

First, Cytyc's arguments in the *Xoft* case regarding the meaning of "inner spatial volume" do not contradict its proposed construction of the term "apparatus volume" in this case. As a threshold matter, the "inner spatial volume" is not a claim element in the '142 patent, and the '142 patent was not asserted in the *Xoft* litigation. As a result, differences in construction are permissible for wholly different terms based upon a different disclosure. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) ("[W]hen an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a

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[17] It is inappropriate to construe the term "apparatus volume" without resort to the surrounding language "three-dimensional apparatus volume configured to fill an interstitial void . . . and define an inner boundary of the target tissue being treated." *See Phillips*, 415 F.3d at 1314. Therefore, while Hologic may refer to the term "apparatus volume," Hologic does so merely by way of shorthand for "three-dimensional apparatus volume configured to fill an interstitial void . . . and define an inner boundary of the target tissue being treated."

differentiation in the meaning of those terms."). Although the '142 patent is a continuation-in-part of the '813 and '204 patents at issue in *Xoft*, (1) the claim terms are different, and (2) the intrinsic evidence for the '142 patent demonstrates that the term "apparatus volume" is not to be limited to a geometric volume. Thus, SenoRx places undue and misguided reliance on the prior construction of the '813 and '204 patents. *See, e.g.*, *Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc.*, 248 F.3d 1303, 1315 (Fed. Cir. 2001) (refusing to use intrinsic evidence from parent application pertaining to a claim term different than the term under consideration); *cf. Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (citing *Jonsson v. The Stanley Works,* 903 F.2d 812, 817-818, (Fed.Cir.1990) for the proposition that "[w]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents *that contain the same claim limitation*" (emphasis added)).

Moreover, there is in actuality no conflict between the position taken by Hologic in this case for the term "apparatus volume" and the position taken by Cytyc in the *Xoft* case for the term "inner spatial volume." Similar to the '142 patent, the '813 and '204 patents speak of an "inner spatial volume" with reference to a structure that defines it. *See, e.g.,* '813 patent, claim 2 ("wherein said inner spatial is an inner closed, chamber defined by a further radiation transparent wall"); '204 patent, claim 9 ("wherein the inner spatial volume is an inner closed, distensible chamber defined by a further radiation transparent wall"). Thus, the "inner spatial volume" is not simply a volume of space but it also has a surface or boundary such that there can be a "predetermined spacing" between it and the structure that defines the "outer spatial volume." *See, e.g.,* '813 patent, claim 1, element c; '204 patent, claim 3.

Second, as noted above, the intrinsic record demonstrates that the inventors did not intend for the term "apparatus volume" to be interpreted strictly and literally as a "region of space," but rather, with reference to a structure composed of the expandable outer surface. Thus, rather than requiring the rigid, literal reading SenoRx seeks to impose on the term "apparatus volume," the claims "can and should be interpreted as the patentees intended," *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520

F.3d 1358, 1363 (Fed. Cir. 2008), with the meaning of the term "apparatus volume" being "the three-dimensional geometric solid composed of an expandable outer surface."

Third, the claim language shows that Hologic's interpretation is the correct one. The expandable outer surface element, e.g., a balloon, "defines" (i.e., composes) the apparatus volume. '142 Patent, 8:63-64. In other words, the phrase "expandable outer surface defining . . ." makes clear that "three-dimensional apparatus volume" is to be understood with reference to the tangible structure that creates or defines—hence the use of the modifiers "three-dimensional" and "apparatus" with the word "volume." Thus, as the term "steel" modified the term "baffles" in the claim term "steel baffles" in *Phillips*, 415 F.3d at 1314, the term "expandable outer surface" modifies the term "apparatus volume" by conferring upon it structural features, i.e., three dimensions for filling an interstitial void and surface area for defining the inner boundary of the target tissue. *See ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) ("[T]he context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms."). Hologic's proposed construction gives effect to all of the claim language and does not render any portion of it superfluous or nugatory. *Cf. Merck & Co. v. Teva Pharms USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (adopting construction that avoids rendering language superfluous). Moreover, Hologic's interpretation includes certain disclosed embodiments, whereas, as SenoRx points out in its motion for summary judgment of invalidity of claim 1, its interpretation would result in an inoperable device and would exclude all of the embodiments disclosed in the '142 patent. SenoRx lacks the "highly persuasive evidentiary support" for such a construction. *NeoMagic Corp.*, 287 F.3d at 1074.

2. "Located So As To Be Spaced Apart From the Apparatus Volume" – Once the Term "Apparatus Volume" Is Properly Construed, the Term "Spaced Apart" Is Clear

When the term "apparatus volume" (in the phrase "three-dimensional apparatus volume configured to fill an interstitial void . . . and define an inner boundary of the target tissue being treated") is properly construed with reference to the "expandable outer surface" element that defines it, the proper meaning of the term "located so as to be spaced apart from the apparatus volume" is clear. Verhey Decl. ¶ 24. "Spaced apart" means "located so as to be not on or touching the apparatus

volume," *i.e.*, the surface area of the apparatus volume that defines the inner boundary of the target tissue to be treated. Dkt. No. 134 at 19-20 (Hologic's Opening Claim Construction Brief). Aside from the arguments it asserts with respect to the term "apparatus volume," SenoRx offers no justification for its construction of "spaced apart"—which would exclude all preferred embodiments and potentially render the claim invalid.[18] Dkt. No. 130 at 23 (SenoRx's Opening Claim Construction Brief). As set forth above, those arguments have no merit. Under the proper construction of the "apparatus volume" terms, the "spaced apart" term "can and should be interpreted as the patentees intended," *Ortho-McNeil Pharm.*, 520 F.3d at 1363, to mean "located so as to be not on or touching the apparatus volume."

B. "Asymmetrically Located and Arranged Within the Expandable Surface" - Means Not on the Longitudinal Axis ('142 Patent, Claim 1)

Every reference to "asymmetry" in the '142 refers to the longitudinal axis of the expandable surface – *i.e.*, if a radiation source is not on the longitudinal axis, the source is "asymmetric." Hologic's proposed construction of the term "asymmetrically located and arranged within the expandable surface" says exactly that: "located and arranged so as not to be on the longitudinal axis of the expandable surface element." Dkt. No. 134 at 23-4 (Hologic's Opening Claim Construction Brief). SenoRx's only comment with respect to this claim term is that its arguments "substantially track those advanced in connection with the 'predetermined asymmetric isodose curves with respect to the apparatus volume.'" (discussed immediately below) Dkt. No. 130 at 25 (SenoRx's Opening Claim Construction Brief). Not so. SenoRx's arguments with respect to the "predetermined asymmetric isodose curves" pertain to the frame of reference by which the isodose curves are determined in advance not to be symmetrical. Those arguments are not directly applicable here, where it is the "radiation source" that is "asymmetrically located and arranged within the expandable surface." '142 patent, 9:3-5.

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[18] As pointed out above, the '813 and '204 patents similarly claim a "predetermined spacing" between the "inner spatial volume" and the structure defining the "outer spatial volume." This "spaced apart" relationship would make no sense if "volume" were read literally, as SenoRx urges, only as a "region of space" and not including also the surface or boundary of the "inner spatial volume."

The intrinsic evidence dictates that Hologic's construction is the correct one - and that SenoRx's should be rejected. The '142 patent's abstract (which is relevant to claim construction, *Hill-Rom Co., Inc. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1341 n.* (Fed. Cir. 2000) ("We have frequently looked to the abstract to determine the scope of the invention")), describes two embodiments. In the first embodiment, "the asymmetric isodose curves are created in the target tissue by shaping or locating the radiation source so as to be asymmetrically placed *with respect to the longitudinal axis of the apparatus*." '142 Abstract (emphasis added). The second embodiment uses "asymmetric radio opaque shielding" to achieve the asymmetric isodose curves. '142 Abstract. The "longitudinal axis" is repeatedly referred to as the frame of reference by which asymmetrical location and arrangement of the radioactive sources is judged. *See, e.g.*, '142 patent, 2:65-3:1 ("[A]symmetric isodose curves are created in the target tissue by shaping or locating the radiation source so as to be asymmetrically placed with respect to a longitudinal axis of the apparatus."); 3:13-15 (" . . . some of the radioactive particles are farther from the longitudinal axis of the apparatus than others"); 3:17-19 (". . . members being shaped so as to place at least one radioactive particle asymmetrically with respect to the longitudinal axis of the apparatus"); 5:11-12 ("Radiation source 24 has an asymmetric configuration with respect to a longitudinal axis 38 of the instrument 10."). The foregoing passages emphatically rebut SenoRx's conclusory allegation (reached with no analysis of the specification) that Hologic seeks to add a limitation to the claim term. To the contrary, Hologic's construction of the term "asymmetrically located and arranged . . ." as meaning "located and arranged so as not to be on the longitudinal axis of the expandable surface," in light of the specification, is the only proper construction – and should be adopted. Verhey Decl. ¶ 25.

C. "Predetermined Asymmetric Isodose Curves" ('142 Patent, Claims 1 & 8)

SenoRx's proposed construction—and its justification for that construction—appear to focus on the wrong frame of reference. As discussed immediately above, the claims require a "radiation source" to be "asymmetrically located and arranged within the expandable surface," and that term means "located and arranged so as not to be on the longitudinal axis of the expandable surface." *See supra.* As a direct consequence of this asymmetric location and arrangement of the radiation source,

"predetermined asymmetric isodose profiles" are created. *See, e.g.*, Abstract ("Asymmetric isodose curves are created . . . by shaping or locating the radiation source so as to be asymmetrically placed with respect to the longitudinal axis."); 2:65-3:1 (similar); 3:13-15 (similar); 3:17-19 (similar). Moreover, as the specification repeatedly states, the asymmetry of an isodose curve is adjudged from the longitudinal axis of the apparatus volume—not based on the shape of the apparatus volume.[19] *See, e.g.*, '142 Patent, 5:19-25; 5:14-18; 3:1-6. Thus, Hologic's construction—the one that aligns the language of the claim with the disclosure of the '142 patent—is the correct one. Verhey Decl. ¶ 26.

III. SENORX'S CONSTRUES THE "PLURALITY" TERMS TOO NARROWLY – DIVORCED FROM THE ACCOMPANYING CLAIM LANGUAGE AND SPECIFICATIONS

Contrary to SenoRx's suggestion, the parties do not dispute the meaning of the word "plurality." The dispute here involves the claim terms "plurality of radioactive solid particles" and "plurality of solid radiation sources" - as those phrases are used in the patents-in-suit. SenoRx's position is a classic example of construing claim terms in isolation – divorced from both the claim language in which they appear and the remainder of the specification. SenoRx clings to particular embodiments of the claimed inventions described in the specification (*see* Fig. 5 of the '813 patent) – insisting that the "plurality" claim terms are limited to those embodiments. Further, wherever the word "plurality" appears in the claims, SenoRx contends the specifications of each patent-in-suit impose a temporal limitation on the claim—*i.e.*, requiring that multiple radiation particles or sources to be

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[19] To support its flawed argument, SenoRx unfairly capitalizes on what appears to have been a misinterpretation of Figures 3 and 3A of the '142 patent by Dr. Verhey, made during his deposition. Dkt. No. 130 at 25, lines 5-14 (SenoRx's Opening Claim Construction Brief); Dkt. No. 130:16 at 146:13-17 (Dr. Verhey's Deposition Transcript). Figures 3 and 3A are different views of the same device **50**; Figure 3 is a side-view and Fig. 3A is an end view, looking straight down the longitudinal axis of the device. '142 patent, col. 3:66-67, col. 4:1-2. The isodose curve **64** produced by this device is shown only in Figure 3A, the end view, as a dotted line. *Id.,* col. 6:36-38. Understood together with the corresponding passage of the specification, it is clear that the asymmetry of the isodose curve **64** is defined with respect to the longitudinal axis of the device, which would appear as a point in the center of element **56**. *Id.,* col. 6:42-46 ("By providing extending portions **58, 60** having radioactive particles in the indicated co-planar relationship, areas of reduced dosage can be created ***on opposed sides of the device*** . . .").

present "at the same time." The specifications provide no support for adding such a limitation. Once again, SenoRx seeks to narrow the inventions by importing examples from the written description into the claims. SenoRx's constructions should be rejected.

A. "Plurality of Radioactive Solid Particles Placed At Predetermined Locations" ('813 Patent, Claim 12) and "Plurality of Solid Radiation Sources" ('204 Patent, Claim 17)

This Court already addressed the "plurality" claim language in the Xoft litigation – and concluded that these terms mean what they say. Dkt. No. 135-6 at 11-12 (Claim Construction Order in Xoft litigation). Hologic agrees. Not surprisingly, SenoRx disagrees. SenoRx defines the two phrases slightly differently but both proposed constructions include the following limitations: (1) "two or more separate" particles / sources within the expandable surface element (2) "at the same time." Dkt. No. 130 at 26-29 (SenoRx's Opening Claim Construction Brief). SenoRx couches this dispute as a disagreement over the meaning of plurality – as that term is typically used in patent parlance. It is not. SenoRx's proposed constructions conflict with the meaning of these terms in light of the surrounding claim language and the specifications, and should be rejected. Verhey Decl. ¶¶ 27-29.

First, with regard to both the "two or more separate" and "at the same time" limitations, SenoRx seeks to import aspects of preferred embodiments into the claims by requiring that discrete radiation sources be present and used simultaneously. *See* '813 patent, Fig. 5. This, of course, is improper unless the specification makes clear that the preferred embodiments *are the invention*. *See, e.g.*, *Afga Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1376 (Fed. Cir. 2006) (refusing to read the term "stack" as limited to "horizontal stacks," even though only horizontal stacks were shown in the patent). "Without any indication beyond the necessary depiction to suggest limiting the invention to this single embodiment, the broader language of the claims cannot carry that unexpressed and unintended (at the time of patent drafting) limitation." *Id.* at 1377. The specification of the '813 patent provides no basis for limiting the claims to the disclosed embodiments. Nor does the '204 patent, which refers to the invention shown in Figure 4 as "a further embodiment," 5:1, and that "desired isodose profiles . . . can also be obtained, *for example*, by strategic placement of a plurality of radioactive particle sources" 5:32-36 (emphasis added). Thus, the specifications impose no such limitations on the claimed

inventions. *Phillips v. AWH Corp.*, 415 F.3d at 1317 (claims must be given their "broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art").

Second, the claims in which these terms appear teach emitting therapeutic rays from more than one location to achieve "a desired composite radiation profile." *See* '813, claim 12. The objective of these claims, *i.e.* achieving a desired composite radiation profile, can be achieved whether one uses a single particle or source, or twenty particles or sources. Indeed, as Dr. Verhey states, from a dosimetric standpoint, there is no difference between moving a radiation source to multiple locations at different times (known as dwell times) and the embodiments depicted in Fig. 5 of the '813 patent and Fig. 4 of the '204 patent. Verhey Decl. ¶ 28.

Third, as Dr. Verhey explains, at the time the applications that led to the patents-in-suit were filed, the remote afterloaders necessary to practice the multi-core embodiment depicted in Fig. 5 of the '813 patent and Fig. 4 of the '204 patent did not exist. Verhey Decl. ¶ 29. Remote afterloaders capable of stepping a single radionuclide through multiple locations within a brachytherapy balloon applicator, however, were available. This fact conflicts with SenoRx's proposed constructions and the teaching of the specifications that "[t]he solid radiation emitting material **44** can be inserted through catheter **12** on a wire **46**, for example, using an afterloader (not shown)." '204 patent, 4:54-56. In other words, the inventors clearly contemplated that their inventions would be compatible with the afterloaders available at that time, as well as loader technology that might not have yet been developed.

In any event, nowhere does the claim language or the specifications impose a temporal limitation on the "plurality" claims—*i.e.*, requiring that multiple radiation particles or sources be present and utilized "at the same time." That language appears nowhere in the patents. SenoRx provides no justification for drafting such a limitation into the claims.

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Hologic respectfully requests that the Court conclude exactly what it did previously – that the "plurality" claim terms mean exactly what they say.

Dated: May 30, 2008

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By: /s/
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PROOF OF SERVICE

I am employed in the County of San Mateo, State of California. I am over the age of 18 and not a party to the within action. My business address is 1950 University Avenue, 4th Floor, East Palo Alto, California 94303.

On May 30, 2008, I served on the interested parties in said action the within:

PLAINTIFFS' REPLY CLAIM CONSTRUCTION BRIEF

by placing a true copy thereof in a sealed envelope(s) addressed as stated below and causing such envelope(s) to be deposited in the U.S. Mail at East Palo Alto, California.

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I declare under penalty of perjury that I am employed in the office of a member of the bar of this Court at whose direction the service was made and that the foregoing is true and correct.

Executed on May 30, 2008, at East Palo Alto, California.

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